§ 880.5580 Acupuncture needle.

(a) *Identification.* An acupuncture needle is a device intended to pierce the skin in the practice of acupuncture. The device consists of a solid, stainless steel needle. The device may have a handle attached to the needle to facilitate the delivery of acupuncture treatment.

(b) *Classification.* Class II (special controls). Acupuncture needles must comply with the following special controls:

(1) Labeling for single use only and conformance to the requirements for prescription devices set out in 21 CFR 801.109,

(2) Device material biocompatibility, and

(3) Device sterility.

[61 FR 64617, Dec. 6, 1996]

§ 880.5630 Nipple shield.

(a) *Identification.* A nipple shield is a device consisting of a cover used to protect the nipple of a nursing woman. This generic device does not include nursing pads intended solely to protect the clothing of a nursing woman from milk.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[45 FR 69682–69737, Oct. 21, l980, as amended at 59 FR 63011, Dec. 7, 1994]

§ 880.5640 Lamb feeding nipple.

(a) *Identification.* A lamb feeding nipple is a device intended for use as a feeding nipple for infants with oral or facial abnormalities.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807. If the device is not labeled or otherwise represented as sterile, it also is exempt from the good manufacturing practice regulation in part 820, with the exception of §820.180, with respect to general requirements concerning records, and §820.198, with respect to complaint files.

§ 880.5680 Pediatric position holder.

(a) *Identification.* A pediatric position holder is a device used to hold an infant or a child in a desired position for therapeutic or diagnostic purposes, e.g., in a crib under a radiant warmer, or to restrain a child while an intravascular injection is administered.

(b) *Classification.* Class I (general controls). The device is exempt from the good manufacturing practice regulation in part 820, with the exception of §820.180, with respect to general requirements concerning records, and §820.198, with respect to complaint files.

§ 880.5700 Neonatal phototherapy unit.

(a) *Identification.* A neonatal phototherapy unit is a device used to treat or prevent hyperbilirubinemia (elevated serum bilirubin level). The device consists of one or more lamps that emit a specific spectral band of light, under which an infant is placed for therapy. This generic type of device may include supports for the patient and equipment and component parts.

(b) *Classification.* Class II (performance standards).

§ 880.5725 Infusion pump.

(a) *Identification.* An infusion pump is a device used in a health care facility to pump fluids into a patient in a controlled manner. The device may use a piston pump, a roller pump, or a peristaltic pump and may be powered electrically or mechanically. The device may also operate using a constant force to propel the fluid through a narrow tube which determines the flow rate. The device may include means to detect a fault condition, such as air in, or blockage of, the infusion line and to activate an alarm.

(b) *Classification.* Class II (performance standards).

§ 880.5740 Suction snakebite kit.

(a) *Identification.* A suction snakebite kit is a device consisting of a knife, suction device, and tourniquet used for first-aid treatment of snakebites by removing venom from the wound.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[45 FR 69682–69737, Oct. 21, l980, as amended at 59 FR 63011, Dec. 7, 1994]